Kevin H. Marino
John D. Tortorella
MARINO, TORTORELLA & BOYLE, P.C.
437 Southern Boulevard
Chatham, New Jersey 07928-1488
Tel: (973) 824-9300
Fax: (973) 824-8425

Attorneys for Plaintiffs Fennec Pharmaceuticals Inc. & Oregon Health and Science University

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

FENNEC PHARMACEUTICALS INC. and OREGON HEALTH AND SCIENCE UNIVERSITY, Plaintiffs, v. CIPLA LIMITED and CIPLA USA, INC., Defendants.	Case 3:23-cv-00123 **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Fennec Pharmaceuticals Inc. ("Fennec") and Oregon Health and Science University ("OHSU" and, together with Fennec, "Plaintiffs") for its Complaint against Defendants Cipla Limited ("Cipla Ltd.") and Cipla USA, Inc. ("Cipla USA" and, together with Cipla Ltd., "Cipla" or "Defendants") allege as follows:

THE PARTIES

1. Fennec is a Canadian corporation with a principal place of business at 68 TW Alexander Drive, Research Triangle Park, North Carolina 27709. Fennec is a specialty pharmaceutical company dedicated to improving the lives of children with cancer who experience hearing loss associated with chemotherapy. Fennec developed PEDMARK® (sodium

thiosulfate injection), the first and only therapy approved by the U.S. Food and Drug Administration ("FDA") for the prevention of ototoxicity induced by cisplatin chemotherapy in children with localized, non-metastatic solid tumors. In the United States, Fennec sells PEDMARK® single-dose vials. Fennec owns all right, title, and interest in U.S. Patent Nos. 11,291,728 ("the '728 patent") and 11,510,984 ("the '984 patent") directed to sodium thiosulfate formulations such as PEDMARK®. In addition, Fennec is the exclusive licensee of U.S. Patent No. 10,596,190 ("the '190 patent" and, together with the '728 and '984 patents, "the Asserted Patents"), directed to the use of sodium thiosulfate formulations such as PEDMARK® after the administration of cisplatin to reduce of the risk of ototoxicity induced by cisplatin in pediatric patients with localized, non-metastatic solid tumors.

2. OHSU is a public corporation of the state of Oregon validly existing under ORS § 353 *et seq.*, with a principal place of business at 3181 SW Sam Jackson Park Rd, Portland, Oregon 97239. OHSU is Oregon's only public academic health center. OHSU treats the most complex health needs and has a research hub that develops lifesaving therapies. OHSU owns the '190 patent, which it has exclusively licensed to Fennec.

3. On information and belief, Defendant Cipla Ltd. is a corporation organized and existing under the laws of India, having its corporate offices and principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

4. On information and belief, Defendant Cipla USA is a corporation organized and existing under the laws of Delaware. Its principal place of business is at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. On information and belief, Cipla USA is a wholly-owned subsidiary of Cipla Ltd.

5. On information and belief, Cipla Ltd. and Cipla USA collaborate with respect to the manufacture, regulatory approval, market, sale, and/or distribution of generic pharmaceutical products. On information and belief, Cipla Ltd. and Cipla USA are agents of one another or operate in concert as integrated parts of the same business group.

6. On information and belief, Cipla Ltd. in collaboration with Cipla USA manufactures and distributes generic pharmaceutical products for sale in the State of New Jersey and throughout the United States.

NATURE OF THE ACTION

7. This action arises under the patent laws of the United States, Title 35, United States Code, § 100 *et seq*., including 35 U.S.C. §§ 271(a), (b), (c), (e), and (f), based upon Cipla's infringement of at least claim 1 of the '728 patent, at least claim 1 of the '984 patent, and claim 1 of the '190 patent, which cover sodium thiosulfate formulations such as PEDMARK® and their use with cisplatin to reduce of the risk of ototoxicity induced by cisplatin in pediatric patients with localized, non-metastatic solid tumors.

8. The active ingredient in PEDMARK® is sodium thiosulfate ("STS"). Eight grams of sodium thiosulfate anhydrous is provided in 100 mL solution with 0.025 grams boric acid in each vial of PEDMARK®. The molecular weight of sodium thiosulfate anhydrous is 158.11 g/mol; the molecular weight of boric acid is 61.83 g/mol. Thus, each vial of PEDMARK® contains about 0.5 M sodium thiosulfate anhydrous and about 0.004 M boric acid. PEDMARK® is a preservative-free solution with a pH between 7 and 9; sodium hydroxide and hydrochloric acid may have been used for pH adjustment. Altogether, the composition in each vial contains less than 0.05% borate ions.

9. The recommended dose of PEDMARK® is based on surface area according to actual body weight as summarized in the following table:

Actual Body Weight	PEDMARK® Dose
Less than 5 kg	10 g/m^2
5 to 10 kg	15 g/m^2
Greater than 10 kg	20 g/m^2

10. PEDMARK® is administered as an intravenous infusion over 15 minutes, following cisplatin infusions that are 1 to 6 hours in duration. PEDMARK® is administered about 6 hours after completion of a cisplatin infusion.

11. Fennec is the holder of New Drug Application No. 212937 for PEDMARK® (sodium thiosulfate injection), single-use vial, for intravenous use, which the FDA approved on September 20, 2022, to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors.

12. The '728, '984, and '190 patents are listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") in connection with PEDMARK® and the related NDA. The '190 and '728 patents were listed in the Orange Book on or around October 6, 2022. The '984 patent was listed in the Orange Book on or around December 14, 2022.

13. On information and belief, Defendants acted collaboratively and in concert to file Abbreviated New Drug Application ("ANDA") No. 218028 (the "Cipla ANDA"), under 505(j) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), *i.e.*, 21 U.S.C. § 355(j), seeking approval to commercially manufacture, use and/or sell generic single-use vials of sodium thiosulfate for reducing the risk of ototoxicity, induced by cisplatin chemotherapy in pediatric patients with localized, non-metastatic solid tumors ("Cipla's ANDA Product").

14. On information and belief, Defendants acted collaboratively and in concert to prepare and submit the Cipla ANDA and continue to act collaboratively and in concert to pursue FDA approval of the Cipla ANDA and to seek to market Cipla's ANDA Product.

15. On information and belief, Defendants rely on material assistance from each other to manufacture, market, distribute, offer for sale, and/or sell generic drugs in the U.S. market, including in the State of New Jersey. On information and belief, Defendants intend to act collaboratively and in concert to commercially manufacture, market, distribute, import into the United States, offer for sale, and/or sell Cipla's ANDA Product, in the event FDA approves the Cipla ANDA.

16. On information and belief, Defendants acted collaboratively and in concert to make and include in the Cipla ANDA certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications") that, in its opinion and to the best of its knowledge, the '190, '984, and '728 patents are invalid, unenforceable, and/or will not be infringed by Cipla's ANDA Product.

17. Fennec and OHSU received written notice of the Cipla ANDA and Paragraph IV Certification as to the '190 and '728 patents on or around December 1, 2022 ("Notice Letter I"), which was dated November 30, 2022, along with an enclosed statement of alleged factual and legal bases for stating that the '190 and '728 patents are invalid, unenforceable, and/or will not be infringed by Cipla's ANDA Product (the "Detailed Statement I"). The Detailed Statement I, however, does not allege or provide any factual bases to assert that the '190 or '728 patents are unenforceable.

18. Fennec and OHSU received written notice of the Cipla ANDA and Paragraph IV Certification as to the '984 patent on or around January 6, 2023 ("Notice Letter II"), which was dated January 5, 2023, along with an enclosed statement of alleged factual and legal bases for stating that the '984 patent is invalid, unenforceable, and/or will not be infringed by Cipla's ANDA Product (the "Detailed Statement II"). The Detailed Statement II, however, does not

allege or provide any factual bases to assert that the '984 patent is unenforceable.

19. This action is being commenced within 45 days of receipt of the Notice Letter I.

20. Cipla has infringed one or more claims of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A) of the filing of the Cipla ANDA with a Paragraph IV Certification and seeking FDA approval of the Cipla ANDA before the expiration of the Asserted Patents or any extensions thereof.

21. Cipla has infringed one or more claims of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A) with the filing of the Cipla ANDA, including any amendments or supplements thereof, seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States of Cipla's ANDA Product before the expiration of the Asserted Patents or any extensions thereof. Cipla will infringe one or more claims of the Asserted Patents under 35 U.S.C. § 271(a), (b), (c) or (f) should it engage in, induce, or contribute to the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Cipla's ANDA Product before the expiration of the Asserted Patents or any extensions thereof.

JURISDICTION

22. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq*., and this Court has subject matter jurisdiction over Fennec's and OHSU's patent infringement claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

23. This Court has personal jurisdiction over Cipla Ltd. under Fed. R. Civ. P. 4(k) because, on information and belief, Cipla Ltd. is organized under the laws of India and because, on information and belief, Cipla Ltd. maintains continuous and systematic contacts with New Jersey through its United States subsidiary Cipla USA, which has its principal place of business in Warren, New Jersey, and regularly and continuously conducts business within this state.

24. Alternatively, should Cipla Ltd. contest jurisdiction in this forum, this Court has personal jurisdiction over Cipla Ltd. under Fed. R. Civ. P. 4(k)(2) because, on information and belief, Cipla Ltd. is not subject to jurisdiction in any State's courts of general jurisdiction and because exercising jurisdiction is consistent with the United States Constitution and laws, including because Cipla Ltd. has sufficient contacts with the United States that relate to the claims in this case.

25. This Court has personal jurisdiction over Cipla USA because its principal place of business is in Warren, New Jersey, and also because Cipla USA has purposely availed itself of the rights and benefits of the State of New Jersey, has engaged in systematic and continuous contacts with the State of New Jersey, and regularly and continuously conducts business within this State. Cipla USA has placed its products in the stream of commerce for distribution and consumption in New Jersey. It derives substantial revenue from selling pharmaceutical products throughout the United States, including New Jersey.

26. This Court also has personal jurisdiction over each Defendant because this suit arises from and relates to their activities that are, and will be, directed to New Jersey. On information and belief, following any FDA approval of the Cipla ANDA, Cipla will market and sell Cipla's ANDA Product that is the subject of the infringement claims in this action in the State of New Jersey and throughout the United States, including in this Judicial District.

27. On information and belief, Cipla, directly and through their subsidiaries, affiliates, or agents, are in the business of manufacturing generic pharmaceuticals that they distribute or have distributed in the State of New Jersey and throughout the United States.

28. On information and belief, Defendants acted in collaboration and in concert to prepare and file the Cipla ANDA intending to seek to market Cipla's ANDA Product

nationwide, including within this Judicial District.

29. On information and belief, Cipla plans to market and sell Cipla's ANDA Product that is the subject of the infringement claims in this action in the State of New Jersey, and throughout the United States, including within this Judicial District, to list Cipla's ANDA Product on the State of New Jersey's prescription drug formulary, and to seek Medicaid reimbursement for sales of Cipla's ANDA Product in the State of New Jersey, either directly or through one or more of Cipla's subsidiaries, agents, and/or alter egos.

30. On information and belief, Defendants acting in collaboration and in concert, have committed, or aided, abetted, induced, contributed to, and/or participated in the commission of the tortious act of patent infringement that will lead to foreseeable harm and injury to Fennec and OHSU, who developed, obtained FDA-approval for, manufactured and/or distributed PEDMARK® for sale and use throughout the United States, including in this Judicial District.

31. On information and belief, Cipla knows and intends that, if approved, Cipla's ANDA Product will be distributed and sold in New Jersey and thereby displacing sales of PEDMARK®, causing injury to Fennec and OHSU. On information and belief, Cipla Ltd. and Cipla USA intend to take advantage of their established channels of distribution in New Jersey for the sale of Cipla's ANDA Product.

32. This Court also has personal jurisdiction over Cipla Ltd. and Cipla USA because their contacts within this Judicial District are continuous and systematic. On information and belief, Cipla Ltd., in collaboration with Cipla USA, develops, manufactures, seeks approval for, and sells FDA-approved generic pharmaceutical products that are regularly marketed, distributed, and sold in New Jersey and throughout the United States. Thus, on information and belief, Cipla Ltd. and Cipla USA do substantial business in New Jersey, derive substantial

revenue from New Jersey, and engage in other persistent courses of conduct in New Jersey. These continuous and systematic contacts, including, but not limited to, those described above and below, are more than sufficient for this Court to exercise personal jurisdiction over Cipla Ltd. and Cipla USA.

33. Although this court has personal jurisdiction over Cipla Ltd. for at least the reasons set forth above, in the absence of such personal jurisdiction in any single state, a foreign entity such as Cipla Ltd. is subject to jurisdiction throughout the United States. *See* Fed. R. Civ. P. 4(k)(2); *see also Merial Ltd.* v. *Cipla Ltd.*, 681 F.3d 1283, 1293–94 (Fed. Cir. 2012).

34. On information and belief, Cipla Ltd. has admitted, consented to, or declined to contest the jurisdiction of this Court and/or has availed itself of this Court's rights, benefits, and privileges by asserting claims and counterclaims in prior District of New Jersey actions. *See, e.g.*, *Par Pharmaceutical, Inc. et al.* v. *Cipla Ltd. et al.*, No. 2:22-cv-02814 (D.N.J. May 13, 2022); *Teva Branded Pharmaceutical Products R&D, Inc. et al.* v. *Cipla Limited*, 2:20-cv-14890 (D.N.J. Oct. 23, 2020); *Celgene Corporation* v. *Cipla Limited*, No. 2:20-cv-07759 (D.N.J. June 24, 2020).

35. On information and belief, Cipla USA has admitted, consented to, or declined to contest the jurisdiction of this Court and/or has availed itself of this Court's rights, benefits, and privileges by asserting claims and counterclaims in prior District of New Jersey actions. *See, e.g.*, *Cubist Pharmaceuticals LLC f/k/a Cubist Pharmaceuticals, Inc.*, v. *Cipla USA, Inc. et al.*, No. 3:19-c-v12920 (D.N.J. May 24, 2019); *Valeant Pharmaceuticals North America LLC* v. *Cipla Ltd. and Cipla USA Inc.*, No. 3:19-cv-00988 (D.N.J. Jan. 23, 2019); *Merck, Sharp & Dohme Corp. et al.* v. *Cipla USA Ltd. Inc. et al.*, No. 1:13-cv-04017 (D.N.J. June 27, 2013).

VENUE

36. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b),

1391(c), and 1400(b) against Cipla Ltd. because, inter alia, Cipla Ltd. is incorporated in India and may be sued in any judicial district in the United States in which Cipla Ltd. is subject to the Court's personal jurisdiction. *See In re HTC Corp.*, 889 F.3d 1349, 1357 (Fed. Cir. 2018).

37. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) against Cipla USA because, inter alia, Cipla USA has a regular and established place of business in Warren, New Jersey and has committed acts of infringement in New Jersey, at least by participating in the submission of Abbreviated New Drug Application No. 218028 in New Jersey.

THE PATENTS-IN-SUIT

U.S. Patent No. 11,291,728

38. The allegations above are incorporated herein by reference.

39. Fennec Pharma owns the '728 patent entitled "Anhydrous Sodium Thiosulfate and Formulations Thereof." The USPTO duly and legally issued the '728 patent on April 5, 2022. The '728 patent names Thomas Claiborne Lovelace, Joseph Alexander Moore, Christopher McKinnon Lee, and Daniel Logan Kirschner as inventors. All named inventors assigned the '728 patent to Fennec Pharma. A true and correct copy of the '728 patent is attached to this Complaint as Exhibit 1.

40. The '728 patent claims a pharmaceutical composition comprising aqueous anhydrous sodium thiosulfate at a concentration of about 0.5 M and about 0.004 M boric acid.

U.S. Patent No. 11,510,984

41. The allegations above are incorporated herein by reference.

42. Fennec Pharma owns the '984 patent entitled "Anhydrous Sodium Thiosulfate and Formulations Thereof." The USPTO duly and legally issued the '984 patent on November 29, 2022. The '984 patent names Thomas Claiborne Lovelace, Joseph Alexander Moore, III,

Christopher McKinnon Lee, and Daniel Logan Kirschner as inventors. All inventors assigned the '984 patent to Fennec Pharma. A true and correct copy of the '984 patent is attached to this Complaint as Exhibit 2.

43. The '984 patent claims a pharmaceutical composition comprising aqueous anhydrous sodium thiosulfate at a concentration of about 0.5 M and borate ions of less than 0.05%.

U.S. Patent Nos. 10,596,190

44. The allegations above are incorporated herein by reference.

45. OHSU owns the '190 patent, entitled "Method for Reducing Ototoxicity in Pediatric Patients Receiving Platinum-Based Chemotherapy." The USPTO duly and legally issued the '190 patent on March 24, 2020. The '190 Patent names Edward A. Neuwelt as the sole inventor, who assigned the '190 patent to OHSU. A true and correct copy of the '190 patent is attached to this Complaint as Exhibit 3.

46. Fennec is the exclusive licensee of the '190 patent.

47. The '190 patent is the subject of an *Inter Partes* review proceeding before the United States Patent and Trademark Office's Patent Trial and Appeal Board filed by Hope Medical Enterprises, Inc. on October 29, 2021, and instituted May 9, 2022. The '190 patent IPR has been assigned docket number IPR2022-00123.

48. The '190 patent claims a method of reducing ototoxicity in a pediatric patient of about five years of age or under by administering cisplatin to treat localized and non-metastatic tumors administered on between about 1 and 5 days per cycle and sodium thiosulfate given each dose of the cisplatin on between about 1 and 5 days per cycle, about six hours after the administration of the cisplatin.

COUNT I
(INFRINGEMENT OF THE '728 PATENT)

49. The allegations above are incorporated herein by reference.

50. Cipla Ltd., in collaboration and concert with Cipla USA, filed the Cipla ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Cipla's ANDA Product before the expiration of the '728 patent, and any extensions thereof.

51. The Notice Letter I states that the Cipla ANDA was filed to obtain approval to manufacture, use, offer to sell, and sell Cipla's ANDA Product before the expiration of the '728 patent. The Notice Letter I represents that the Cipla ANDA was submitted with a Paragraph IV Certification that the '728 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Cipla's ANDA Product. The Notice Letter I does not allege that the '728 patent is unenforceable.

52. Cipla has actual knowledge of the '728 patent.

53. The PEDMARK® Label states that 8 grams of sodium thiosulfate anhydrous is provided in 100 mL solution with 0.025 grams boric acid in each vial of PEDMARK®. As the molecular weight of sodium thiosulfate anhydrous and boric acid is 158.11 g/mol and 61.83 g/mol, respectively, each vial of PEDMARK® contains about 0.5 M sodium thiosulfate anhydrous and about 0.004 M boric acid. Sodium hydroxide and hydrochloric acid may have been used for pH adjustment to achieve a pH between 7 and 9.

54. The PEDMARK® formulation, as a composition comprising about 0.5 M sodium thiosulfate anhydrous and about 0.004 M boric acid, is claimed, among other things, in at least claim 1 of the '728 patent.

55. Thus, PEDMARK® and any corresponding generic STS injection are covered by

at least claim 1 of the '728 patent, and Fennec has the right to enforce the '728 patent and sue for infringement thereof.

56. The '728 patent is listed in the Orange Book for PEDMARK®.

57. On information and belief, if the Cipla ANDA is approved, Cipla will make, use, offer for sale, sell, or import Cipla's ANDA Product in a manner that would infringe at least claim 1 of the '728 patent.

58. On information and belief, the Cipla ANDA essentially copies the PEDMARK® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, promotes, and/or suggests that physicians, prescribers, and/or patients infringe at least claim 1 of the '728 patent.

59. On information and belief, if the Cipla ANDA is approved, physicians, prescribers, and/or patients will follow the instructions in the proposed label for Cipla's ANDA Product and thereby infringe at least claim 1 of the '728 patent.

60. PEDMARK® and any corresponding generic STS injection formulation is not a staple article of commerce and has no substantial approved uses that do not infringe at least claim 1 of the '728 patent. On information and belief, Cipla's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claim 1 of the '728 patent.

61. Cipla has infringed at least claim 1 of the '728 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Cipla ANDA to FDA seeking to obtain approval for Cipla's ANDA Product, which is covered by at least claim 1 of the '728 patent, before the expiration of the '728 patent.

62. The commercial manufacture, use, offer to sell, sale, distribution, or importation

of products under the Cipla ANDA would infringe directly or contribute to or induce infringement of at least claim 1 of the '728 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

63. Fennec seeks entry of an order requiring that Cipla amend its Paragraph IV Certification in the Cipla ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(vii)(A).

64. Fennec seeks entry of an order declaring that Cipla has infringed at least claim 1 of the '728 patent by virtue of submitting the Cipla ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

65. Fennec seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Cipla ANDA be a date that is not earlier than the expiration of the '728 patent or any later expiration of exclusivity for the '728 patent to which Fennec becomes entitled.

66. Fennec seeks entry of an order declaring that Cipla will infringe one or more claims of the '728 patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Cipla's ANDA Product before the expiration of the '728 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

67. Fennec will be irreparably harmed if Cipla is not enjoined from infringing, actively inducing, or contributing to the infringement of at least claim 1 of the '728 patent. Pursuant to 35 U.S.C. § 283, Fennec is entitled to a permanent injunction against further infringement. Fennec does not have an adequate remedy at law.

68. On information and belief, Cipla's Detailed Statement I setting forth the factual and legal bases for its opinion regarding infringement and validity of the '728 patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Fennec is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

69. To the extent Cipla commercializes Cipla's ANDA Product prior to the expiration of the '728 patent, Fennec will also be entitled to damages under 35 U.S.C. § 284.

COUNT II
(INFRINGEMENT OF THE '984 PATENT)

70. The allegations above are incorporated herein by reference.

71. Cipla Ltd. in collaboration and concert with Cipla USA, filed the Cipla ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Cipla's ANDA Product before the expiration of the '984 patent, and any extensions thereof.

72. The Notice Letter II states that the Cipla ANDA was filed to obtain approval to manufacture, use, offer to sell, and sell Cipla's ANDA Product before the expiration of the '984 patent. The Notice Letter II represents that the Cipla ANDA was submitted with a Paragraph IV Certification that the '984 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Cipla's ANDA Product. The Notice Letter II does not allege that the '984 patent is unenforceable.

73. Cipla has actual knowledge of the '984 patent.

74. The PEDMARK® Label states that 8 grams sodium thiosulfate anhydrous is provided in 100 mL solution with0.025 grams boric acid in each vial of PEDMARK®. As the molecular weight of sodium thiosulfate anhydrous and boric acid is 158.11 g/mol and 61.83 g/mol, respectively, each vial of PEDMARK® contains about 0.5 M sodium thiosulfate anhydrous and about 0.004 M boric acid. Sodium hydroxide and hydrochloric acid may have been used for pH adjustment to achieve a pH between 7 and 9. Altogether, the composition in each vial contains less than 0.05% borate ions.

75. The PEDMARK® formulation, as a composition comprising about 0.5 M sodium

thiosulfate anhydrous and less than 0.05% borate ions, is claimed, among other things, in at least claim 1 of the '984 patent.

76. Thus, PEDMARK® and any corresponding generic STS injection are covered by at least claim 1 of the '984 patent, and Fennec has the right to enforce the '984 patent and sue for infringement thereof.

77. The '984 patent is listed in the Orange Book for PEDMARK®.

78. On information and belief, if the Cipla ANDA is approved, Cipla will make, use, offer for sale, sell, or import Cipla's ANDA Product in a manner that would infringe at least claim 1 of the '984 patent.

79. On information and belief, the Cipla ANDA essentially copies the PEDMARK® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, promotes, and/or suggests that physicians, prescribers, and/or patients to infringe at least claim 1 of the '984 patent.

80. On information and belief, if the Cipla ANDA is approved, physicians, prescribers and/or patients will follow the instructions in the proposed label for Cipla's ANDA Product and thereby infringe at least claim 1 of the '984 patent.

81. PEDMARK® and any corresponding generic STS injection formulation is not a staple article of commerce and has no substantial approved uses that do not infringe at least claim 1 of the '984 patent. On information and belief, Cipla's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claim 1 of the '984 patent.

82. Cipla has infringed at least claim 1 of the '984 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Cipla ANDA to FDA seeking to

obtain approval for Cipla's ANDA Product, which is covered by at least claim 1 of the '984 patent, before the expiration of the '984 patent.

83. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Cipla ANDA would infringe directly or contribute to or induce infringement of at least claim 1 of the '984 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

84. Fennec seeks entry of an order requiring that Cipla amend its Paragraph IV Certification in the Cipla ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(vii)(A).

85. Fennec seeks entry of an order declaring that Cipla has infringed at least claim 1 of the '984 patent by virtue of submitting the Cipla ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

86. Fennec seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Cipla ANDA be a date that is not earlier than the expiration of the '984 patent or any later expiration of exclusivity for the '984 patent to which Fennec becomes entitled.

87. Fennec seeks entry of an order declaring that Cipla will infringe at least claim 1 of the '984 patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Cipla's ANDA Product before the expiration of the '984 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

88. Fennec will be irreparably harmed if Cipla is not enjoined from infringing, actively inducing, or contributing to the infringement of at least claim 1 of the '984 patent. Pursuant to 35 U.S.C. § 283, Fennec is entitled to a permanent injunction against further infringement. Fennec does not have an adequate remedy at law.

89. On information and belief, Cipla's Detailed Statement II setting forth the factual

and legal bases for its opinion regarding infringement and validity of the '984 patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Fennec is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

90. To the extent Cipla commercializes Cipla's ANDA Product before the expiration of the '984 patent, Fennec will also be entitled to damages under 35 U.S.C. § 284.

COUNT III
(INFRINGEMENT OF THE '190 PATENT)

91. The allegations above are incorporated herein by reference.

92. Cipla Ltd., in collaboration and concert with Cipla USA, filed the Cipla ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Cipla's ANDA Product before the expiration of the '190 patent, and any extensions thereof.

93. The Notice Letter I states that the Cipla ANDA was filed to obtain approval to manufacture, use, offer to sell, and sell Cipla's ANDA Product before the expiration of the '190 patent. The Notice Letter I represents that the Cipla ANDA was submitted with a Paragraph IV Certification that the '190 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Cipla's ANDA Product. The Notice Letter I does not allege that the '190 patent is unenforceable.

94. Cipla has actual knowledge of the '190 patent.

95. The FDA-approved PEDMARK® Label instructs physicians, prescribers, and/or patients that "PEDMARK is indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors."

96. The PEDMARK® Label further instructs physicians, prescribers, and/or patients that "[t]he recommended dose of PEDMARK is based on surface area according to actual body

weight as summarized in Table 1.

Table 1. Recommended Dose for PEDMARK

Actual Body Weight	PEDMARK® Dose
Less than 5 kg	10 g/m^2
5 to 10 kg	15 g/m^2
Greater than 10 kg	20 g/m^2

Administer PEDMARK as an intravenous infusion over 15 minutes, following cisplatin infusions that are 1 to 6 hours in duration."

97. The PEDMARK® Label further instructs physicians, prescribers, and/or patients to "[a]dminister PEDMARK 6 hours after completion of a cisplatin infusion."

98. Thus, the use of PEDMARK® and any corresponding generic STS injection to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older is covered by claim 1 of the '190 patent. Fennec and OHSU have the right to enforce the '190 patent and sue for infringement thereof.

99. The '190 patent is listed in the Orange Book for PEDMARK®.

100. On information and belief, if the Cipla ANDA is approved, Defendants will make, use, offer for sale, sell, or import Cipla's ANDA Product in a manner that would infringe claim 1 of the '190 patent.

101. On information and belief, the Cipla ANDA essentially copies the PEDMARK® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, promotes, and/or suggests that physicians, prescribers, and/or patients infringe claim 1 of the '190 patent.

102. On information and belief, if the Cipla ANDA is approved, physicians, prescribers, and/or patients will follow the instructions in the proposed label for Cipla's ANDA Product and thereby infringe claim 1 of the '190 patent.

103. PEDMARK® and any corresponding generic STS injection formulation is not a staple article of commerce and has no substantial approved uses that do not infringe claim 1 of the '190 patent. On information and belief, Cipla's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe claim 1 of the '190 patent.

104. Cipla has infringed claim 1 of the '190 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Cipla ANDA to FDA seeking to obtain approval for Cipla's ANDA Product, which is covered by claim 1 of the '190 patent, before the expiration of the '190 patent.

105. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Cipla ANDA would infringe directly or contribute to or induce infringement of claim 1 of the '190 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

106. Fennec and OHSU seek entry of an order requiring that Cipla amend its Paragraph IV Certification in the Cipla ANDA to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III Certification") as provided in 21 C.F.R. § 314.94(a)(12)(vii)(A).

107. Fennec and OHSU seek entry of an order declaring that Cipla has infringed claim 1 of the '190 patent by virtue of submitting the Cipla ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

108. Fennec and OHSU seek entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Cipla ANDA be a date that is not earlier than the expiration of the '190 patent or any later expiration of exclusivity for the '190 patent to which Fennec and OHSU become entitled.

109. Fennec and OHSU seek entry of an order declaring that Cipla will infringe claim

1 of the '190 patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Cipla's ANDA Product before the expiration of the '190 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

110. Fennec and OHSU will be irreparably harmed if Cipla is not enjoined from infringing, actively inducing, or contributing to the infringement of claim 1 of '190 patent. Pursuant to 35 U.S.C. § 283, Fennec and OHSU are entitled to a permanent injunction against further infringement. Fennec and OHSU do not have an adequate remedy at law.

111. On information and belief, Cipla's Detailed Statement I setting forth the factual and legal bases for its opinion regarding infringement and validity of the '190 patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Fennec and OHSU are entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

112. To the extent Cipla commercializes Cipla's ANDA Product before the expiration of the '190 patent, Fennec and OHSU will also be entitled to damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor against Defendants and grant the following relief:

A. an adjudication that Defendants have infringed directly, contributed to the direct infringement of, and/or induced the direct infringement of one or more claims of each of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A), by submitting to FDA the Cipla ANDA, including any amendments or supplements thereof, to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Cipla's ANDA Product before the expiration of the Asserted Patents, or any later period of exclusivity to which Plaintiffs are or may become entitled;

B. a judgment declaring that Cipla will infringe directly, contribute to the direct

infringement of, and/or induce the direct infringement of one or more claims of each of the Asserted Patents under 35 U.S.C. §§ 271(a), (b), (c) and/or (f) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States Cipla's ANDA Product before the expiration of the Asserted Patents, or any later period of exclusivity to which Plaintiffs are or may become entitled;

C. an order requiring that Defendants amend its Paragraph IV certification to a Paragraph III certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

D. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Cipla ANDA for Cipla's ANDA Product be a date that is not earlier than the latest date of the expiration of the Asserted Patents or any later period of exclusivity to which Plaintiffs are or may become entitled;

E. a permanent injunction enjoining Defendants, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the Asserted Patents or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Cipla ANDA;

F. an order enjoining Defendants, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the Asserted Patents, contributing to, or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of Cipla's ANDA Product;

G. an assessment of pre-judgment and post-judgment interest and costs against Defendants, together with an award of such interest and costs, in accordance with

35 U.S.C. § 284;

H. an award to Plaintiffs of their attorneys' fees incurred in connection with this lawsuit pursuant to 35 U.S.C. § 285; and

I. such other and further relief as this Court may deem just and proper.

Kevin H. Marino
John D. Tortorella
MARINO, TORTORELLA & BOYLE, P.C.
437 Southern Boulevard
Chatham, New Jersey 07928-1488
Tel: (973) 824-9300
Fax: (973) 824-8425

Attorneys for Fennec Pharmaceuticals Inc. & Oregon Health and Science University

Of Counsel:

Nicholas Groombridge†
Jennifer H. Wu
Eric Alan Stone
Josephine Young†
Naz E. Wehrli†
Eliza P. Strong†
GROOMBRIDGE, WU, BAUGHMAN & STONE LLP
565 Fifth Ave
Suite 2900
New York, NY 10017
(332) 269-0030

Dated: January 10, 2023